JUL 10 2012

Exhibit 5 510(k) Summary

Date of Summary Preparation: January 20, 2012

1. Submitter and US Official Correspondent

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2. Establishment Registration Number

3005843418

3. Device Information

Proprietary/Trade Name: Computed tomography X-ray system / VOLUX 21C
Common/Usual Name: Computed tomography X-ray system
Classification Name: X-ray, Tomography, Computed
Product Code: OAS
Device Class: Class II per regulation 21 CFR 892.1750

4. Equivalent Legally Marketed Device

< PaX-Reve3D Plus >

Manufacturer: Vatech Co., Ltd.
Device Name: PaX-Reve3D Plus
510(k) Number: K102124 (Decision Date: Oct. 22, 2010)

5. Description of the Device

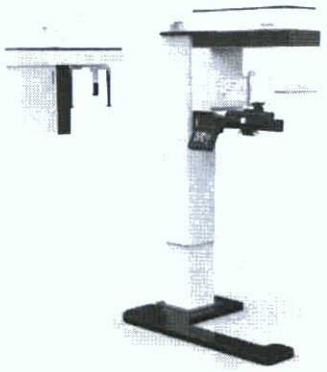
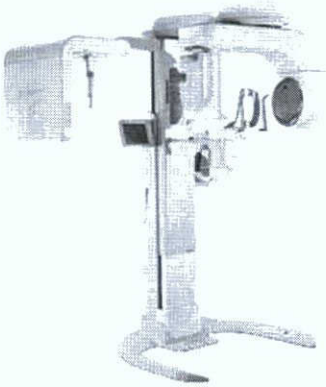
VOLUX 21C is a diagnostic imaging system which consists of multiple image acquisition modes; panorama, cephalometry and computed tomography. VOLUX 21C designed for dental radiography of the oral and craniofacial anatomy. VOLUX 21C is equipped with extra-oral x-ray detector based on CMOS digital X-ray detector, CT & panoramic radiography with an extra-oral x-ray tube. CMOS digital X-ray detector is used to capture scanned image in 3D for obtaining diagnostic information for craniofacial surgery or other treatments. And VOLUX 21C can also be operated as the cephalometric dental x-ray system based on CCD X-ray detector.

Items \ Product	VOLUX 21C
X-ray Source	High Frequency, Stationary tube, 60 ~ 110 kV 5 ~ 7mA (CT, Panorama) 60 ~ 110 kV 20mA (Cephalo)
Focal Spot	0.5mm , 1.5mm
Image Detector	CMOS flat panel(CT, Panorama) CCD(Cephalo)
FOV	CT : 145mm x 85mm Panorama : 144 x 330mm Cephalo : 240mm x 300mm
Image Acquisition (CT)	360°
Scan time / exposure time	CT : 15.8 sec Panorama : 17.1 sec Cephalo : 0.5~2 sec
Power Voltage / Input power	120V~, 60Hz, 4.8 KVA
Total filtration	2.5mmAl (inherent :0.5mmAl, Added : 2.0mmAl)
Patient position	Standing
Reconstruction type	Cone beam (CT) Fan beam (Panorama)
Reconstruction time	2.5 minutes
Main body weight	300 kg ± 5kg
Main body dimension	1449 x 2111.5 x 2307 mm

6. Indications for use

VOLUX 21C is a Computed tomography X-ray system intended to produce panoramic, cephalometric or cross-sectional images of the oral and craniofacial anatomy on a real time basis by computer reconstruction of x-ray image data from the same axial plane taken at different angles. It provides diagnostic images of the anatomic structures by acquiring 360°rotational image sequences of oral and craniofacial area for a precise treatment planning in adult and pediatric care. The device is operated and used by physicians, dentists and x-ray technicians.

7. Substantial equivalence chart

Name	VOLUX 21C	PaX-Reve3D Plus
Manufacturer	GENORAY Co., Ltd.	Vatech Co., Ltd.
510(k) No.	-	K102124
Figure		
Indications for use	VOLUX 21C is a Computed tomography X-ray system intended to produce panoramic, cephalometric or cross-sectional images of the oral and cranioifacial anatomy on a real time basis by computer reconstruction of x-ray image data from the same axial plane taken at different angles. It provides diagnostic images of the anatomic structures by acquiring 360°rotational image sequences of oral and craniofacial area for a precise treatment planning in adult and pediatric care. The device is operated and used by physicians, dentists and x-ray technicians.	PaX-Reve3D Plus is a Computed tomography X-ray system intended to produce panoramic, cephalometric or cross-sectional images of the oral and cranioifacial anatomy on a real time basis by computer reconstruction of x-ray image data from the same axial plane taken at different angles. It provides diagnostic details of the anatomic structures by acquiring 360° rotational image sequences of oral and cranioifacial area for a precise treatment planning in adult and pediatric care The device is operated and used by physicians, dentists, and x-ray technicians.
Performance Specification	Panoramic, Cephalometric and Computed tomography	Panoramic, Cephalometric and Computed tomography
Input Voltage	120V~	110V~
Tube Voltage	60 ~ 110 kV	50-100kV
Tube Current	5 ~ 7mA (CT, Panorama) 20mA (Cephalo)	2-10mA
Focal Spot Size	0.5mm, 1.5mm	0.5mm
Exposure Time	0.5-17s (Various)	0.5-24s (Various)

Size of Imaging Volume	CT : 145mm x 85mm Panorama : 144mm x 330mm Cephalo : 240mm x 300mm	150x150mm, 120x80mm, 80x60mm, 50x50 mm
Slice Width	0.14mm min	0.1mm min
Total Filtration	2.5mmAl	2.8mmAl
Pixel Size	CT : 150 μm Panorama : 150 μm Cephalometric : 160 μm	CT : 200 μm Panorama : 100 μm Cephalometric : 127μm
Image Receptor	CT with Flat Panel Detector Cephalo with CCD Detector	CT with Flat Panel Detector
Chin Rest	Equipped Chinrest	Equipped Headrest
Performance Specification	Computed tomography	Computed tomography
Software	DICOM 3.0 Format compatible	DICOM 3.0 Format compatible
Anatomical Sites	Maxillofacial	Maxillofacial

Indications for use, safety characteristics for panoramic and non-clinical performance for panmetric of Volux 21C and PaX-Reve3D Plus are similar.

8. Safety, EMC and Performance data comparison to Predicate
   - Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1, IEC 60601-1-1, IEC 60601-1-3, IEC 60601-2-7, IEC 60601-2-28, IEC 60601-2-32 and IEC 60601-2-44 were performed.
   - EMC testing was conducted in accordance with standard IEC 60601-1-2.
   - FDA Guidance "Guidance for the submissions of 510(k)'s for Solid State X-ray Imaging Devices" was performed.
   - Acceptance test according to IEC 61223-3-4 and IEC 61223-3-5 was performed.

   All test results were satisfactory.
   The result of bench and clinical evaluation indicates that the new device is as safe and effective as the predicate devices.

9. Conclusion
   In reference to the comparison information provided in substantial equivalence chart, most of function and electronic feature are similar in both products. We believe that the VOLUX 21C is safe, effective and substantially equivalent in clinical & technical expect with the predicate devices, Pax-Reve3D Plus.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

GENORAY Co., Ltd.
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Sales & Marketing Manager
Genoray America Inc.
1073 N. Batavia Street, Suite A
ORANGE CA 92867

JUL 10 2012

Re: K120263
Trade/Device Name: Computed tomography X-ray system (Model: VOLUX 21C)
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: OAS and MUH
Dated: June 26, 2012
Received: June 28, 2012

Dear Mr. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Exhibit 4 Indications for use

510(k) number (if known): K120263

Device Name: Computed tomography X-ray system (Model: VOLUX 21C)

Indications for Use:

VOLUX 21C is a Computed tomography X-ray system intended to produce panoramic, cephalometric or cross-sectional images of the oral and cranioifacial anatomy on a real time basis by computer reconstruction of x-ray image data from the same axial plane taken at different angles. It provides diagnostic images of the anatomic structures by acquiring 360°rotational image sequences of oral and craniofacial area for a precise treatment planning in adult and pediatric care. The device is operated and used by physicians, dentists and x-ray technicians.

Prescription Use ___V___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K120263